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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,927	09/15/2000	Marvin J. Slepian	MJS 101	3540

7590 09/20/2002

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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

4C

Office Action Summary

Application No.

09/662,927

Applicant(s)

SLEPIAN, MARVIN J.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 19, 22, 23, 27, 28 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 19, 22, 23, 27, 28 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-9, 19, 22, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,146,029 to Ellinwood, Jr. Ellinwood, Jr. discloses an implantable device which includes a sensor and a housing which stores and evaluates data and dispenses medication. The medication dispenser causes the device to undergo a configurational change in the device by movement of its parts while dispensing. The sensors can detect pH changes, ionic changes, glucose, and electrical

changes. In regard to claims 4-5 and 22, telemetry means is employed to transmit information to various peripheral devices.

3. Claims 1-9, 19, 22-23 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,248,080 to Miesel et al. Miesel et al. teaches an implantable medical device which telemeters stored data or real-time-sensed data to an external device to derive intracranial gage pressure. (Abstract of Miesel et al.). The medical device includes a temperature or pressure sensor implanted into the brain. The implantable device includes a means of receiving, storing, and transmitting the signals to an external device. The system includes the implantable medical device (IMD) delivering an antibiotic, an antiviral agent, an anti-inflammatory agent, a vaccine, or a drug. (column 6, lines 27-42 of Miesel et al.). In regard to claim 1, Miesel et al. discloses that the delivery of therapy can include actions such as shunt opening or closing or a valve opening or closing. (column 13, line 56 to column 14, line 6 of Miesel et al.). The device is considered to undergo a configurational change when the delivery or cessation of delivery of a therapy occurs since such an action accompanies physical movement of parts. In regard to claims 2-3, the IMD includes RAM. (column 9, lines 1-20 of Miesel et al.). In regard to claims 4-5, telemetry can be employed. (column 8, lines 43-53 of Miesel et al.). In regard to claim 9, temperature, pH, or oxygen saturation can be calculated. (column 9, lines 45-52 of Miesel et al.). In regard to claim 23 and 31-32, the system can include transmission of alarms and information via telephone, hardwire, cell phone, satellite, or internet. (column 17, lines 57-65 of Miesel et al.).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,146,029 to Ellinwood, Jr. as applied to claim 1 in view of U.S. Patent 5,411,551 to Winston et al. Ellinwood, Jr. does not teach the use of a sensor on a stent. Ellinwood, Jr. teaches that glucose level sensors can be used. (column 7, lines 1-15 of Ellinwood, Jr.). Ellinwood, Jr. does not teach a particular form of glucose sensor. Winston et al. teaches a stent for the sensing of glucose. (Abstract of Winston et al.). The glucose sensor of Winston et al. is the type of sensor that Ellinwood, Jr. suggests that can be used in the implanted device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Ellinwood, Jr. to include the sensor of Winston et al. for determining blood glucose since Ellinwood, Jr. requires a glucose sensor and Winston, Jr. teaches one such sensor. The combination does not teach a sensor which can measure protein deposition or formation of a bacterial film on a biliary stent, an increase in calcification of a urinary stent, or neointimal thickening of an arterial stent. It is well known in the art that the fouling of a sensor will effect the measurements of that sensor. The

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discrepancy of the readings would be a measure of the fouling of the sensor on the stent due to protein deposition or formation of a bacterial film on a biliary stent or an increase in calcification of a urinary stent. A measurement of the fouling up of the sensor would indicate that it is time to change the sensor. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include using the discrepancy of the readings to determine that the sensor on the stent is fouled up since it would indicate that it is time to change the sensor.

Response to Arguments

6. Applicant's arguments filed on 7/22/2002 have been fully considered but they are not persuasive. Applicant argues that Miesel et al. fails to show any structure that would actuate the implantable device so as to change its configuration. The Examiner respectfully disagrees. Miesel et al. teaches a therapy device in response to the detection of a predetermined condition or state in the brain (column 10, lines 16-25 of Miesel et al.). Miesel et al. further discloses that the delivery of therapy can include actions such as a shunt opening or closing or a valve opening or closing. (column 13, line 56 to column 14, line 6 of Miesel et al.). The device is considered to undergo a configurational change when a physical action occurs in the delivery device such as the opening or closing of a valve since the movement of the parts changes the configuration of the device.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,964,993 to Blubaugh, Jr. et al. discloses that microbial contamination by bacteria and fungi is likely to disrupt implanted glucose sensors.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

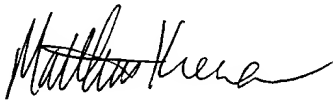
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

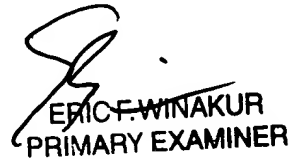
0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736
September 17, 2002



ERIC F. WINAKUR
PRIMARY EXAMINER